



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



15 MAR 2017

MEMORANDUM FOR SGVT
ATTN: MAJ CARRIE LITKE-WAGER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation presented at/published to International Meeting on Simulation Healthcare, Orlando, FL, 28 January – 1 February 2016 in accordance with MDWI 41-108, has been approved and assigned local file #17052.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
Litke-Wager, Carrie, Major, O-4, SGVT		181 YES <input checked="" type="checkbox"/> NO	C.2015.099d
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MOW Form 3039 must be submitted for review and approval.) A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation			
7. FUNDING RECEIVED FOR THIS STUDY? <input checked="" type="checkbox"/> YES 181 NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: 181 YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input checked="" type="checkbox"/> YES 181 NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input checked="" type="checkbox"/> YES 181 NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: 181 DOMESTIC RELEASE <input checked="" type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
<input checked="" type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input checked="" type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
181 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) International Meeting on Simulation Healthcare, Orlando, FL, 28Jan2016-01Feb2016			
<input checked="" type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
<input checked="" type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)			
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?			
<input checked="" type="checkbox"/> YES 181 NO ASSIGNED FILE#		DATE	
13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC)			
DATE			
December 20, 2016			
14. 59 MOW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)		15. DUTY PHONE/PAGER NUMBER	
Litke-Wager, Carrie Ann,R.,carrie.a.litke-wager.mil@mail.mil		210-916-7078	
16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME	FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL
a. Primary/Corresponding Author			INSTITUTION (if not 59 MOW)
Litke-Wager, Carrie	0-4/Major	959CSPS/59MDW/SGVT	
b. Mu, Thornton	0-5/LTC	MCHE-ZDP-N	SAMMC
c. Delaney, Heather	0-4/MAJ	MCHE-ZDP-N	SAMMC
d.			
e.			
17. ISA 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input checked="" type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401.1P, AND 59 MDW 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
18. AUTHOR'S PRINTED NAME, RANK, GRADE		19. AUTHOR'S URE -	20. DATE
Litke-Wager, Carrie Ann, Major, O-4			November 28, 2016
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE		22. APPR'Y? ITY'S SIGN	23. DATE
Mu, Thornton, LTC, Neonatology Program Director			November 28, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED 1/30/2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17052
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26. DATE REVIEWED 3/10/2017	27. DATE FORWARDED TO 502 ISG/JAC
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28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: NO YES If yes, give date. _____ N/A

29. COMMENTS APPROVED DISAPPROVED

IRB approved abstract submitted well after presentation was give. Appropriate disclaimers included and IRB approval included. Approved

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

Kevin Kupferer/GS13/Hum Res Subj Prot Exp

31. REVIEWER SIGNATURE

KUPFERER.KEVIN.R

32. DATE

3/10/2017

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED

.T086667270

34. DATE FORWARDED TO 59 MDW/PA

35. COMMENTS APPROVED (In compliance with security and policy review directives.) DISAPPROVED

36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

37. REVIEWER SIGNATURE

38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED

March 14, 2017

40. DATE FORWARDED TO 59 MDW/SGVU

March 15, 2017

41. COMMENTS APPROVED (In compliance with security and policy review directives.) DISAPPROVED

42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs

43. REVIEWER SIGNATURE

INUMA.KEVIN.MITSUGU.

1296227613

44. DATE

March 15, 2017

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED

46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL

YES NO COULD NOT BE REACHED LEFT MESSAGE

47. COMMENTS APPROVED DISAPPROVED

Hypothesis/Research Question/Objective

Despite receiving standardized Neonatal Resuscitation Program (NRP) training, providers frequently fail to comply with NRP guidelines during neonatal resuscitation. The most common deviations include ineffective ventilation technique, difficulty completing intubation, and improper medication administration. In an effort to address these performance gaps we devised a teaching paradigm, called 'Task-Oriented Role Assignment', in which we have delegated a specific set of tasks to be performed within the traditional role assignments used during NRP. We hypothesize that this method will improve communication and task delegation within the resuscitation team, resulting in improved NRP performance.

Methods

Participants include health care providers completing NRP. A sample size of 72 is needed to detect an effect size of 0.8 standard deviations. Participants are randomized to either the control group, and receive NRP only, or the study group, and receive NRP with additional training on the use of 'Task-Oriented Role Assignment'. This paradigm consists of 5 roles: team leader, cardiac chief, airway chief, line/medication chief, and recorder, with each role given a subset of pre-determined tasks. We have incorporated the mnemonic, 'B CALMR', into a visual aid. Participants are then randomized into smaller groups to participate in standardized NRP simulations using a high-fidelity patient simulator. The scenarios are video recorded and then evaluated for task completion and team behaviors by two blinded investigators. Participants complete a demographic survey and pre- and post-course self-assessment questionnaires in which they rate their ability to perform various aspects of NRP.

Results

To date we have enrolled 24 subjects with 12 participants in each group. Demographics were statistically similar between the control and study groups with the exception that a statistically higher number of 'real-world' resuscitations were reported among the control group (median 4.7 vs. 1.2; p=0.03). The control group rated themselves statistically higher than the study group in most categories of the pre-(mean difference 0.75-0.91, p=0.004-0.4) and post-course (mean difference 0.76-1.09, p=0.00007-0.004) self-assessments. The post-course assessments for both groups showed statistically significant improvement in each category when compared to pre-course assessments. For the control group the mean difference in scores ranged between 1.17-1.5 (p= 0.000001-0.0004), and in the study group the mean difference in scores ranged from 1-1.4 (p=0.000009-0.0006). The difference in score improvement between the two groups was not statistically significant.

Conclusion

Regardless of group assignment, participants perceived their ability to perform NRP to be greater after receiving any NRP education. The control group had higher self-assessment scores than the study group. The significance of this is unclear, and needs to be correlated with the NRP task and team behavior performance scores, which are pending at this time.

Disclaimer

The views expressed are those of the author(s)/presenter(s) and do not reflect the official views or policy of the Department of Defense or its Components.



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
REGIONAL HEALTH COMMAND CENTRAL (PROVISIONAL)
4070 STANLEY ROAD, SUITE 121
JBSA FORT SAM HOUSTON, TEXAS 78234-2715

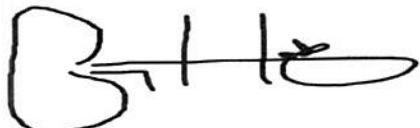
MCSR-CS

15 June 2016

MEMORANDUM FOR: Maj Carrie Litke-Wager, MD
FROM: Brooke Army Medical Center Institutional Review Board
PROJECT TITLE: A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation
REFERENCE #: C.2015.099d
SUBMISSION TYPE: Continuing Review/Progress Report
ACTION: APPROVED
IRB APPROVAL DATE: 15 June 2016
EXPIRATION DATE: 16 June 2017
REVIEW TYPE: Expedited
PROJECT STATUS: Active, Open to Enrollment

1. Congratulations! The Brooke Army Medical Center (BAMC) Institutional Review Board (IRB) reviewed and APPROVED continuation of your aforementioned protocol and supporting documents. The research continues to be judged Minimal Risk. Your protocol and continuing review application was reviewed for regulatory compliance under Expedited Review, in accordance with 32CFR219.110 (b)(1) Federal Register Categories 6 and 7. Applicable OHRP (under 45CFR46), FDA (under 21CFR50 and 56) and HIPAA (45CFR160 and 164) regulations were also consulted, as appropriate.
2. The following minor changes in research were also requested and approved in accordance with 32CFR§219.110(b)(2).
 - P01 removed Dr Ward as statistician. Respective changes now reflected in P01 Version 2, 13 June 2016.
3. This protocol will automatically expire on June 16, 2017. If you plan to continue beyond this date, the required continuing review progress report is due to the BAMC IRB no later than six (6) weeks prior to expiration. Please Note: If a Data Safety and Monitoring Board (DSMB) has been named, please submit its most recent report with your annual Continuing Review. The IRB will attempt to assist you by sending a reminder; however, submission of the continuing review report is your responsibility. Failure to submit the report on time will result in the expiration of your protocol and a requirement to cease all research activities until the protocol can be reapproved.

4. If at any time you have questions regarding your responsibilities as a Principal Investigator, please do not hesitate to contact Amy Holstein at 210-916-8227 or amy.l.holstein.civ@mail.mil. On behalf of the entire IRB, we wish you much success with your research protocol. We look forward to reviewing the progress of your study in the coming months.

A handwritten signature in black ink, appearing to read "Amy L. Holstein".

AMY L. HOLSTEIN
RN, MPH, CCRP, CIP
Designated Expedited Review IRB Member